

REVIEWER GUIDELINES

NIDDK P01 PROGRAM PROJECTS

The guidelines available here use language posted in the original funding opportunity announcement (FOA) and do not replace or modify the criteria established in the full announcement. If you have any questions, contact the Scientific Review Officer (SRO) in charge of the review panel. SRO contact information for your application can be found in [eRA Commons](#).

GENERAL INSTRUCTIONS FOR PREPARATION OF P01 CRITIQUE

Each reviewer is expected to read the complete application in addition to their assigned review components. You will all comment on the merit of the entire Program Project as a whole and will need to be familiar with the entire application. A key point to remember is that beyond the scores assigned to each project and core, a single impact score is assigned to the entire Program Project as a whole. It is the "Overall Score" that will be used to guide the Program staff of the NIDDK and our National Advisory Council in their funding decisions.

The Overall Score is not just an average of the scores assigned to the projects and cores. Rather, you should factor in whether there is synergy and cohesiveness between the individual components. Is the whole greater than the sum of its parts? Are the projects simple stand-alone R01 type applications or together will they achieve something more by being combined with each other in a program? Does the Principal Investigator have sufficient experience and skill to lead a program of this size and complexity?

GENERAL REVIEW CONSIDERATIONS

For a program project application to be assigned a priority score, at least three component projects must extend for the duration of the program project. NIH policy does not allow recommendations to remove a project or core to improve the overall impact score of a P01. All projects and cores MUST be scored, otherwise the entire P01 is not scored. The NIDDK is interested in supporting only the best research; individual research projects that are relatively lower in merit may not be funded under the "umbrella" of the program project mechanism. It is primarily for this reason that each project will be assigned a separate priority score, taking into consideration only its merit as an individual research project. It is important that each project fits and contributes to the theme of the overall program project, but this factor should be judged separately and should have no bearing on a project's individual score. Instead, these considerations will be addressed later with respect to the merit of the overall program project.

It is expected that individual components, in order to receive funding, will not represent significantly poorer research than is being funded by the R01 mechanism. However, a project whose score is somewhat poorer than currently funded R01 grants may benefit greatly from inclusion in the overall program project, whereby synergism with other components and use of core facilities significantly enhance its value. Conversely, such a project might provide certain elements that greatly enhance other projects in the overall program project. Such considerations would be expected to have an impact on the overall priority score assigned by the reviewers to the program project.

All applications must request and be reviewed for 5 years of project period support. While one or more projects may be recommended for less than 5 years, only in very unusual circumstances may the entire program project be recommended for less than 5 years.

In the case of the review of a competing continuation (renewal) application, the progress made during the past period of funding is also an important consideration in the review of projects and cores.

Requested core budgets may need to be adjusted downward if it is recommended that some of the individual projects utilizing their services are reduced in scope. Therefore, it is important for both the applicant and the reviewer to address the contribution of the core to each project in both scientific and budget terms.

Scientific or budgetary overlap, if identified in an application, should be noted in a statement separate from the critique and should not be considered in the evaluation of the application. The Scientific Review Officer will ensure that such issues are documented in the summary statement as an administrative note. Purported overlap must be resolved by NIH staff before an award is made.

Review of Individual Projects

Written Critiques: For each research project, a priority score is assigned based on the criteria for the review of individual research projects. Please enter each criterion score in the Internet Assisted Review (IAR) module and address each review criterion in a separate section under the individual headings shown below and outlined in the Project Critique Template. Refer to Scoring System and Procedure for guidelines. The critique, overall/priority score and the criterion scores must be entered in IAR prior to the review meeting.

The scored review criteria for individual research projects are:

Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s): Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children justified in terms of the scientific goals and research strategy proposed?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. *Although these review criteria do not receive individual scores, they may influence the impact score you assign to a project.* As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Vertebrate Animals. The reviewers (committee) will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection

if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications. For Resubmissions, the reviewers will evaluate the projects as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made.

Renewal Applications. For Renewals, the committee will consider the progress made in the last funding period.

Revision Applications. For revision (competing supplement) applications, consider whether there is a carefully conceived and explained rationale for extension of currently funded projects, and whether there has been sufficient progress made to warrant the extension.

Additional Review Considerations. *These review criteria do not receive individual scores and should not be considered in determining the overall impact score.* As applicable for the project proposed, reviewers will address each of the following:

Applications from Foreign Organizations. Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Resource Sharing Plans: Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Review of Individual Cores

Please address each of review criteria in a separate section using the individual headings shown below and outlined in the Core Critique Template. Only an Overall Impact score should be entered to IAR; individual criterion scores are not provided. As a final outcome, cores receive merit descriptors rather than numeric scores:

The review criteria for the individual cores are:

1. **Utility of the core to the program project;** each core must provide essential facilities or service for two or more projects judged to have substantial scientific merit;
2. **Quality of the facilities or services provided by this core** (including procedures, techniques, and quality control) and criteria for prioritization of usage;
3. **Core Personnel:** (the qualifications, experience, and commitment of the core director and personnel involved in the core; and
4. **Appropriateness of the timetable** in relation to the scope of the proposed research support.

If human subjects, vertebrate animals, or biohazards are to be used in the core, the adequacy of these sections must be assessed and will be considered in determining the score of the individual core.

Renewal applications: the progress made in the last funding period should be considered.

Core Budget: If any changes are recommended, provide a justification along with a specific dollar amount. The budget is not considered while evaluating the scientific merit of the core and does not contribute to the merit.

Review of Overall Program Project

Once all Projects and Cores have been discussed and scored the entire review committee will participate in a discussion of the overall scientific merit of the application. The Chair will initiate the discussion by summarizing points heard during

the evaluations of each project and core. Next the discussion will be open to the group and each reviewer can add points of emphasis or disagreements to the discussion. The Chair of the review panel will prepare the Overall Critique after the meeting concludes using the reviewer critiques for the projects and cores and notes taken during the group discussion of the overall scientific merit of the Program Project.

The relationship and contributions of each research component and core to the overall theme of the program project are discussed and evaluated; these points must be clearly and specifically outlined in the summary statement. This will be a separate consideration which is not determined exclusively by the priority scores of the individual projects.

The overall program project application is evaluated considering the projects, supporting cores, and the administrative structure. For a Program Project to receive an impact score, it must consist of at least three individual projects for the duration of the proposed Program Project period. Each core must provide essential functions or services for at least two of these projects.

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the program project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

1. Specific factors to be evaluated in the consideration of the overall program project are:

- a. Scientific merit of the program as a whole, as well as that of individual projects, and its potential impact on the field;
- b. The evaluation of the overall program in terms of significance, innovation, investigators, approach, and environment;
- c. Scientific gain of combining the component parts into a program project (beyond that achievable if each project were to be pursued separately);
- d. Cohesiveness and multidisciplinary scope of the program and the coordination and interrelationship of all individual research projects and cores to the common theme;
- e. Leadership and scientific ability of the principal investigator/program director and his or her commitment and ability to develop a well-defined central research focus (request of support for sufficient effort to provide effective oversight and administration of the program should be considered); and
- f. Past accomplishments of the program or a demonstrated ability in mounting similar programs.

2. Additional criteria for renewal (competing continuation) applications include:

- a. Progress and achievements specific to this program project since the previous review and the evidence through publications, conferences, etc., that collaboration has occurred;
- b. Evidence that the previous specific aims have been accomplished and that the new research goals are logical extensions of ongoing work;
- c. Previous performance and estimated use of the core(s); and
- d. Justification for adding new projects or cores or for deleting components previously supported.

Final Recommendation

If the overall program project is judged to have sufficient merit, an impact score will be assigned based on the application's merit as a program project. The review committee specifically should address the value of each project to the overall program project and the resultant synergy. This score is not the average of the scores assigned to the individual components.